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BIOTECH BULLETIN

Biotech Bulletin is a bi-monthly publication brought out by Biotech Consortium India Limited (BCIL), a company promoted by the Department of Biotechnology (DBT), Government of India and the All India Financial Institutions which is involved in facilitating accelerated development and commercialisation of biotechnology.

The bulletin is a useful compilation of latest clippings from newspapers, magazines and journals on relevant areas in biotechnology including healthcare, agriculture, market/ collaborations, research and development.

The publication is brought out exclusively for our **Biotech Club Members**.

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Budget 2015: Science & technology gets Rs 7,288 crore boost

THE ECONOMIC TIMES
February 28, 2015

In what could be a major boost to the field of Science and Technology, the government has allocated Rs 7,288 crore in the Union Budget 2015-16 for conducting research, giving a hike of Rs 1,793 crore compared to the budget of 2014-15.

The Ministry of Science and Technology has three sub-departments - Department of S&T (DST), Department of Biotechnology (DBT) and Centre for Scientific and Industrial Research (CSIR).

The DST has received highest allocation of Rs 3,401 crore, while the CSIR, which controls one of the premier scientific reserach centres and laboratories conducting a range of research, has been allocated Rs 2,281 crore and DBT has been allocated Rs 1,606 crore.

Sources, however, added that the increased allocation was subject to revision, which could dampen the spirit. In 2014-15 Budget, the Ministry of S&T was alloted Rs 6,725 crore, but it was revised to Rs 5,495 crore.

The Ministry of Earth Sciences (MoES) has been allocated Rs 1,179 crore in the budget.

Emphasis has been given on Oceanographic Research, for which Rs 669 crore have been alloted, and Rs 425 crore for research in Meteorology.

IPR Think Tank recommends to establish Institute of Excellence to strengthen research and skill building in IP

PHARMABIZ.COM
January 5, 2015

The draft National Intellectual Property Rights (IPR) Policy, submitted recently by the IPR Think Tank to the Department of Industrial Policy and Promotion (DIPP), has recommended to the government to establish a national level Institute of Excellence to strengthen and expand human resources, institutions and capacities for teaching, training, research and skill building in IP.

The proposed Institute of Excellence will provide thought leadership in IP; conduct policy and empirical research; examine trends and developments in the field of IP at the national and international level; support the government in strategic development of IP systems and international negotiations; establish links with similar institutes and experts in other countries for exchange of ideas, information and best practices; and suggest approaches and guidelines for inter-disciplinary human capital development, the Policy says.

It will strengthen and empower RGNIIPM, Nagpur to conduct training for IP administrators and managers in industry and business, academicians, R&D institutions; IP professionals; inventors and civil society; train the trainers and develop training modules; develop links with other similar entities at the international level; and set up state level institutions which will work with RGNIIPM.

The proposed Institute of Excellence will also energise IP Chairs in educational institutes of higher learning to provide high quality teaching and research; and develop teaching capacity and curricula and evaluate their work on performance based criteria. It will introduce IP courses/modules in all major training institutes such as Judicial Academies, National Academy of Administration, Police and Customs Academies, IIFT, Institute for Foreign Service Training, and Forest Training Institutes.

Besides, the Institute of Excellence will create IPR cells and technology development and management units in such institutes; make IP a compulsory subject in all legal educational institutions, NIDs, NIFTs, agricultural universities and management institutes; and progressively introduce IP teaching in schools, colleges and other educational institutions.

The IPR Think Tank in its Policy said that

the proposed Institute of Excellence will facilitate industry associations, inventors and creators associations and IP support institutions to raise awareness of IP issues and for teaching, training and skill building; encourage formulation of institutional IP Policy/Strategy in higher education, research and technical institutions; link IP teaching as part of accreditation mechanism in institutes under the purview of UGC, AICTE/MCI as well as IITs/IIMs; develop distance learning and on-line courses on IP for all categories of users; and strengthen IP teaching, research and training in collaboration with WIPO, WTO, other International Organisations and reputed foreign universities.

Earlier in November the DIPP had constituted the IPR Think Tank headed by Justice (Retd) Prabha Sridevan. Other members of the IPR Think Tank include Pratibha M. Singh, Narendra K. Sabharwal, Punita Bhargava, Rajeev Srinivasan and Dr. Unnat Pandit. ■

IMA, Healthcare Federation of India to develop Code of Ethics for healthcare sector

THE ECONOMIC TIMES
January 15, 2015

Indian Medical Association (IMA) and Healthcare Federation of India (NATHEALTH) will join hands to develop Code of Ethics for the healthcare sector in the country.

IMA and NATHEALTH said they would soon sign a Memorandum of Understanding (MoU) in this regard.

Emphasising the need for a Code of Ethics, President of NATHEALTH, Shivinder Mohan Singh said, "Unethical behavior and business practices are always distressing and especially, in healthcare, as trust is integral to healing. It is imperative that we develop a nationally accepted, unified set of standard value-based practices that would guide the delivery of ethical healthcare services to patients."

An MoU between IMA and NATHEALTH to develop a joint Code of Ethics would be able to support the government's aim of universal healthcare through strong self-regulation.

A joint task-force is already working on the details, he added.

Speaking on the occasion, Dr A Marthanda Pillai, President and Dr K K Aggarwal, Hony Secretary General, IMA said, "Self Code of Ethics is the need of the hour. Our partnership with an inclusive institution like NATHEALTH will help us to achieve the goal of 'Clean Medical World' in collaboration with leaders in the healthcare sector, not only in healthcare delivery but also in other sectors like medical technology providers,diagnostic services, health insurance, healthcare education, healthcare IT, healthcare publishers/communicators and other segments.

"IMA will be able to sensitize its over 2.5 lakh members regarding this Code of Ethics," they added.

Dr Prathap C Reddy, Founder President of NATHEALTH said the last few decades in India have witnessed a revolution in medicine driven by rapidly changing technology and increased access to diagnostic testing and medical care.

"The Code of Ethics being developed jointly by NATHEALTH and IMA resonates with this valued goal and is in recognition of the need for self-regulation by all members of the healthcare ecosystem, he said. ■

Panel on drugs and cosmetic rules decides to form 7 sub-groups

BUSINESS STANDARD
January 22, 2015

A committee formed to examine and recommend amendments in the Drugs and Cosmetic Rules has decided to form seven sub-groups for individual reviewing of various segments like drugs and clinical trials.

"The committee decided that for review of the provisions of the rules, it should be segregated into different segments like drugs, medical devices, clinical trials, biologicals, blood banks and cosmetics.

"Further, the rules related to each sector may be reviewed by a sub-group and the proposed amendments would be recommended.

"Each sub-group would have a nodal person from the industry and a resource person from the Central Drugs Standard Control Organisation (CDSCO)," the minutes of the recent meeting of the committee put up by Health Ministry said.

The government had recently constituted a high-level committee to examine and recommend amendments to the Drugs and Cosmetics Rules, 1945.

"The timeline for giving first round of suggestions and comments for amendment in the said Rules would be January 31, 2015," the minutes stated.

The committee chaired by Joint Secretary (Regulation), Department of Health and Family Welfare met on January 21 and had participation of various industry associations as well.

The committee noted that after the first draft of amended rules is prepared, it would be made available in the public domain and all the stakeholders would again get the opportunity to furnish their comments.

"Consultation with the stakeholders would be an ongoing process and it would be ensured that all the associations, and other stakeholders are included in the process," the minutes said.

Representatives of Industry associations suggested that co-opting academicians and experts from reputed institutes such as AIIMS, Tata Memorial Cancer Hospital, Christian Medical College and others including those who are engaged in the conduct of clinical trials.

The committee has been formed to revisit the Drugs and Cosmetics Rules, 1945 and make recommendations for amending it to make these rules contemporary while keeping in view the requirements of quality, safety and efficacy of medical products, an earlier ministry order had stated.

SC tells govt to spell out protocol on clinical trials

DECCANHERALD
January 14, 2015

The Supreme Court asked the Centre to spell out within four weeks the protocols being followed for experimenting a vaccine on subjects and the subsequent compensation given to them in case of any adverse impact.

A bench of Justice Dipak Misra and Justice P C Pant allowed a plea made by the Centre's counsel R S Suri seeking time to file his response to a contention that recent Parliament Standing Committee has in December last adversely commented over the procedure being followed by the government.

Senior advocate Colin Gonsalves, appearing for petitioner Kalpana Mehta, contended that the 81st report of the standing committee showed how total apathy had been exhibited in experimenting vaccines on young tribal girls in Andhra Pradesh, Telangana and Gujarat.

The bench also asked the government to reply on what steps have been taken to find out the hardships faced by subjects in clinical trials besides compensation in consonance with law. The court posted the matter for further hearing on March 18.

State drug regulators tap USFDA coach to polish skills on good manufacturing

THE ECONOMIC TIMES
January 14, 2015

Indian state drug regulators have started tapping global safety firms which train investigators of the US Food and Drug Administration to brush up skills of their own inspectors.

Gujarat State Food and Drug Control Administration (FDCA) enlisted the Indian arm of Underwriters Labs (UL), a US-headquartered safety consultancy, to coach 45 of its inspectors on good manufacturing practices, its commissioner Hemant Koshia confirmed to ET over phone

UL, with presence in 46 countries, claims to have trained over 36,000 USFDA investigators over the past two-three decades 'in an exclusive partnership'.

The safety firm is also talking to other states with a high concentration of pharma units, including Maharashtra, Uttarakhand and Andhra Pradesh for similar tie-ups. The move comes in the backdrop of a rising number of India-based drugmaking facilities coming under the US regulator's gaze since 2013.

Over 30 India-based drug-making units have been banned from shipping to

the US in the past two years, including those belonging to leading pharma companies such as Sun Pharma, Ranbaxy Labs (in the process of getting acquired by rival Sun), Wockhardt, as the US drug regulator stepped up its scrutiny here.

"Gujarat is home to almost a third of drug production in the country and many of these pharma companies manufacture for the country as well as for exports to developed markets from the same facilities. We would want our inspectors to train with the best, and UL's training is aligned with the vision of the US FDA, the strongest drug and food regulating agency in the world," said Koshia.

He added that besides training on rapidly evolving current good manufacturing practices, Gujarat FDCA has also asked the safety firm to customise its training for Indian needs and environment.

"These are just the first few steps. We are in talks with other states to replicate the model," said Suresh Sugavanam, managing director, UL, South Asia. Besides GMPs, UL would also focus on principles of good documentation while training inspectors.

Many Indian drug manufacturers — small and big have been especially found wanting by the USFDA in this department of maintaining proper recordkeeping and an audit trail.

A total of seven Indian facilities were under import alert (ban on drugs from a plant) imposed by the US regulator in 2011, nine in 2012, and 32 in March 2014, reckons an India Ratings & Research estimate of May 2014. In 2013 alone, the USFDA banned 21 Indian manufacturing facilities from shipping, the highestever for India in any single year. ■

India wants its officials during USFDA inspections at drug units

THE ECONOMIC TIMES
January 11, 2015

Perturbed by Indian drug-makers frequently running into overseas regulatory problems, the government has requested the US health watchdog FDA to allow its officials during inspections of domestic pharma units.

While Indian pharma exports continue to grow and may touch $ 16.5 billion this year, many Indian pharmaceutical companies have faced regulatory action by the US Food and Drug Administration (FDA) in the recent past for alleged violation of 'good manufacturing practices' and other irregularities at the drug facilities in different parts of the country.

In many cases, these companies have been barred from selling their drugs in the US and other countries, although Indian firms account for a significant share of generic drug market in those places.

"US FDA's increased inspections and observations (under 483) also are troubling us. The Ministry of Commerce has taken up the issue seriously. Earlier practice was that whenever they are visiting any Indian site they used to inform us. Now they started coming without any notice.

PV Appaji, Director General Pharmexcil, (Pharmaceuticals Export Promotion Council), under the Ministry of Commerce and Industry also said that India pharma exports may touch $ 16.5 billion this year.

"Cultural differences and body language may sometime widen the gap (during FDA inspection). We are requesting them (FDA) to allow Indian regulators also to be present during the inspections," Appaji told PTI.

Indian pharma exports have come under tremendous pressure in the recent times owing to various import alerts issued by the USA drug regulator on some of the major pharma companies.

Describing India as a nation which is of "particularly important" to US food and drug trade, FDA Commissioner Margaret Hamburg had earlier said inspections are routine part of the regulatory process and what happens in India is consistent with what happens in the US and throughout world.

A number of other Indian drug-makers, including Ranbaxy, Sun Pharma, IPCA Labs, Wockhardt and Dr Reddy's Laboratories were also pulled up by the FDA for one or the other reasons.

The FDA imposed a ban on import of medicines produced at Ranbaxy's India-based factories into the US, the world's biggest drug market. Later, certain drugs produced at its Dewas plant were barred from export to the entire EU region for non-compliance to 'good manufacturing practice norms.

Sun Pharma also faced regulatory heat as the FDA put a ban on import of products made at its Karkhadi plant in Gujarat. Another pharma firm which ran into rough weather was Wockhardt, in whose US facility in Illinois, USFDA found many procedural lapses.

The US health regulator also found nine possible procedural deviations in a manufacturing plant of Dr Reddy's Laboratories during an inspection last year. ■

Maharashtra gives nod for field trial of 5 GM crops

THE ECONOMIC TIMES
January 30, 2015

The Maharashtra government has given 'no objection certificate' for field trial of five genetically modified (GM) crops - brinjal, maize, rice, chickpea and cotton - in the state.

Since June 2011, it has been made mandatory for companies to obtain 'NOC' from the state governments where they want to conduct field tests.

"Barring rubber, the Maharashtra government has given NOC for conducting field trials of GM crops - brinjal, maize, rice, chickpea and cotton," said C D Mayee, member of the committee that suggests the state government on GM crops.

In a meeting the Committee-headed by Anil Kakodkar had given clearance for field test of these five GM crops, he told reporters while releasing a report on 'Global status of biotech crops' by international body ISAAA.

The state government has approved field trial of BT rice and two other rice varieties which are drought tolerant and has nitrogen use efficiency.

Maharasthra is focusing on allowing those GM crops that address the problem of insecticides, weedicide and diseases in crops like rice, cotton, soyabean, groundnut, pigeonpea, brinjal, chilli and others.

Besides Maharasthra, Punjab, Haryana, Delhi and Andhra Pradesh have given NOCs for field trials of some biotech crops, while states like Madhya Pradesh and Rajasthan have banned such research activities. ■

1 in 4 drugs on NPPA price cap list crash by over 40 percent

THE INDIAN EXPRESS
January 21, 2015

Prices of one in four essential drugs that were on the list of 489 formulations covered under the National Pharmaceutical Pricing Authority's drug price control order last year have crashed by over 40 per cent in comparison to the highest price of each of these drugs prevalent prior to the imposition of the price caps.

Apart from these 122 drugs where prices have fallen over 40 per cent, the prices of the remaining 367 formulations — including anti-AIDS and anti-cancer drugs, painkillers, sedatives and steroids — have dropped between 5 per cent and 40 per cent, according to the Department of Pharmaceuticals data.

The findings of the study that covers the impact of the price caps notified up to September 15, 2014, assume importance in the wake of the continuing slugfest between Big Pharma and the drug regulator over the issue of price caps, something that is expected to come up during the course of official discussions during the US President Barack Obama's upcoming visit to India.

Domestic regulations allow the NPPA to fix prices of drugs on a list of essential medicines. The pharmaceutical industry lobby groups had filed two separate lawsuits against the NPPA in July 2014 over its notice to cap the prices of 108 drugs that were not on the government's national list of essential medicines.

The NPPA's powers to cap the prices of non-essential medicines were subsequently revoked by a higher authority, even as the price caps on the 108 drugs continue, while hearings in the cases are underway.

On the industry's contention, the regulator had cited the sharp surge in prices of drugs in India over the last decade as a justification for the intervening by way of the price control order.

There was a reported 40 per cent surge in all drug prices between 1996 and 2006, during when the price of controlled drugs rose by less than 1 per cent even as those in the essential drug list increased by 15 per cent.

The price of drugs that were neither under price control nor under the drugs list rose by 137 per cent.

Out of the 628 essential medicines specified in the Schedule-I of the NPPA's Drug price control order, 2013, the regulator had notified the ceiling prices for 489 medicines up to September 15, 2014, under the provisions of the regulator's order. Till May 2014, the NPPA had fixed ceiling prices of 440 scheduled drugs and since then, ceiling prices were fixed for additional 49 scheduled drugs.

Under the price control order, the 'ceiling price' calculations are based on "market-based data" wherein the "average price to retailer" is considered for pricing. Manufacturers are barred from selling any scheduled drug or formulation at a price higher than the ceiling price fixed by NPPA. ■

Govt plans regulatory pathway to assist pharma companies

THE TIMES OF INDIA
February 2, 2015

In line with Prime Minister Narendra Modi's action plan to enhance ease of doing business in India, the health ministry has proposed a regulatory pathway for pharmaceutical companies conducting clinical trials and planning to launch products in the country.

The ministry has proposed 'pre-submission meetings' to enable technical deliberations between the drug regulator and stakeholders to address concerns even before companies make formal application seeking product approvals or permission for clinical trials.

"Stakeholders feel that there should be a window for technical deliberations with the regulator and subject experts before submission of formal application. This would mean there is a discussion over the regulatory pathway and companies addressing concerns or making applications in a more systematic way fulfilling the requirements," an official said. He added that the exercise would save time and resources for both - the industry as well as the regulator which has to scrutinize several applications in detail.

The idea is to facilitate speedy approvals, while bringing in transparency, accountability and predictability, a latest notice by the Drugs Controller General of India (DCGI), proposing the move, said. DCGI, operating under the health ministry, is the drug quality regulator with a mandate to approve new drugs, clinical trials and medical devices. It also monitors the quality and efficacy of pharmaceutical products sold in the market.

Experts say the move is likely to enhance efficiency in the sector, which has been witnessing muted growth faced with regulatory hurdles and policy uncertainties in the domestic market pegged at over Rs 87,000 crore.

The drug manufacturing industry, one of the top contributors to the country's exports, is a major investment destination and a focus area for the Modi government's 'Make in India' campaign.

However, in the past few years, the sector witnessed a significant slowdown in product approvals, clinical trials approval along with almost a year long ban on foreign investment approvals in the absence of a clear FDI policy for the sector.

Last year, the government said it was aiming to improve India's ranking in the World Bank's 'Ease of Doing Business' index to 50th position in the next two years, even as the country slipped to 142 in 2014 from 134 in the previous year. The World Bank had clarified the rankings were based on data available till May 2014 and did not take into account measures taken by the new government.

Improving India's credentials as a business-friendly destination is likely to help the new government attract much-needed foreign direct investment, experts say.

IIT-M launches Biotechnology Incubator

BUSINESS STANDARD
December 11, 2014

The Indian Institute of Technology, Madras (IIT-M) has launched a Biotechnology Incubator to support the biotechnology start-ups to start their business and grow to a higher level.

The Incubation Cell of IIT-M is currently incubating 30 start ups a year and with the launch of the Incubator and one more incubator to join soon, this is expected to go up to 50 companies a year, said Ashok Jhunjhunwala, faculty-in-charge, IIT-M Research Park and Co-Chairman of IIT-M Incubation Cell.

The Biotech incubator is aimed at heling start-ups and SMEs develop globally competitive products and launch them into the market successfully, said the institution. The biotech start ups require a longer time to break even, at least 10 years, compared to an IT start up which might break even in 3-4 years, said Srikumar Suryanarayanan, CEO, Sea6 Energy, an expert in Biotech sector in the country.

The start ups in the sector would also require costly equipments compared to other start up businesses, to take up their projects properly, he added. The Biotechnology Industry Research Assistance Council, a public sector enterprise, is currently offering support to start ups and SMEs in the sector and currently support 120-130 companies including oveer 100 enterprenuerial ideas.

Four start ups - Purius Nanosystems Pvt Ltd which is working on point-of-care testing devices for single tests for Tuberculosis Bacilli, Malaria, Hepatitis B Virus or panel tests for HIV, FIB-Sol Life Technologies Pvt Ltd which develops low-cost bio fertilisers, Vital Bioscientific Solutions which develop model to simulate a system reaction to a drug and Yaathum Biotech which develops diagnostic test kits to identify full range of drug resistant TB strains in a single test - has been identified as the incubatees for the first phase.

Bluetongue vaccine for cattle launched

BUSINESS LINE
January 8, 2015

India's first vaccine for bluetongue disease that is increasingly afflicting sheep and goat population across the country was launched by the veterinary biological company Indian Immunologicals Ltd.

Bluetongue is a viral disease, which has about 24 viral strains prevalent across the world.

However, in India, only five strains are mostly prevalent, but its incidence in the cattle population is increasing.

"The incidence rate (of this disease) is estimated at 50 per cent of the sheep and goal population in India, with the mortality rate touching almost 30 per cent. India has about 200 million sheep and goat population," said K V Balasubramaniam, Managing Director of IIL, an arm of the National Dairy Development Board.

The incidence of this disease is much higher compared to other susceptible species, including camels, with several outbreaks reported from the sheep belt in southern and western States. There is no preventive mechanism till date and routine drugs are used for treatment.

The symptoms include fever and blue tongue.

AFFORDABLE PRICING

IIL developed this vaccine in collaboration with Indian Council of Agriculture Research and Tamil Nadu University of Veterinary and Animal Sciences.

"We took about three years to develop this vaccine. Although we are the first to come out with this vaccine, we still have kept the price at an affordable 5 per dose," he told mediapersons.

India would require about 60 million doses to vaccinate the vulnerable sheep and goat population.

IIL has developed the capacity to produce this requirement at its Hyderabad facility, which produced the first batch of three million doses.

The vaccine is given to four-month-old cattle population, followed by a booster dose three months later and one dose every year from then.

Meningitis: Indian vaccine will protect infants also

THE HINDU
January 15, 2015

A meningitis A vaccine (MenAfriVac) manufactured by Serum Institute of India, Pune was approved by WHO a few days ago for use in infants in sub-Saharan African populations. The vaccine will be introduced as part of the routine immunisation programme.

"In the four years since its introduction in Africa, MenAfriVac has had an immediate and dramatic impact in breaking the cycle of meningitis A epidemics," a WHO release said. The vaccine has already been used in those aged 1-29 years. But with the WHO's approval, the vaccine can be given to infants thereby "protecting million more children at risk of the deadly disease." About 200,000 people suffer from meningitis every year in the region. The disease kills 20,000 to 25,000 people in the region every year.

"Like in the case of measles, not many meningitis cases are seen in children younger than one year," said Dr. Suresh Jadhav, Executive Director of Serum Institute. "A mother, who has had meningitis, transmits the meningitis antibodies to newborns and these antibodies protect them for one year." Every individual living in the meningitis belt (which stretches from Senegal in the west to Ethiopia in the east) gets infected with meningitis before the age of 29 years and hence mothers invariably carry

antibodies against the disease.

The WHO has approved the use of a 5 microgram dose of the vaccine for children, which will be administered when theyare nine months old. Immunisation at nine months will help achieve sustainable disease control following mass campaigns that target people belonging to the 1-29 age group.

Explaining the rationale for choosing to immunise at ninth month, Dr. Jadhav said: "It's one opportunity to treat both measles and meningitis," he said. Measles vaccination is also given to children at nine months of age.

A booster dose will be given when the child is 12-18 months old. According to Dr. Jadhav, the first meningitis dose will protect a child for five years and a booster dose will confer lifelong protection.

Though a single campaign has been carried outto cover a large population in 15 countries, those born after the campaign have not received the MenAfriVac vaccine and are hence vulnerable to meningitis infection. But with the introduction of the vaccine as part of the immunisation schedule, these children will also be protected.

The campaign mode will continue till 2017 in 3-4 countries per year. The current demand for the vaccine is 50-55 million. Once the campaign comes to an end, the demand will be directly proportional to the number of children born in the meningitis-endemic countries. "Twenty-five million children are born each year in these endemic countries. So 50 million doses will be the demand per year [as two doses are to be given to each child]," he said.

SERUM'S ACHIEVEMENT

The Serum Institute had successfully made the vaccine heat stable so that it can remain outside the cold chain at temperatures less than 40 degree C for up to four days without the potency getting affected. Before it was made heat stable, the vaccine had to be kept in a cold chain at 2-8 degree C at all time. The vaccine was made heat stable by freeze-drying it.

The Serum Institute successfully demonstrated that the stability and potency of the meningitis vaccine remained intact even when exposed to higher temperature. The heat stable nature of the vaccine proved to be a game changer in meningitis control and made it possible to cover a large number of people through the campaign mode.

"It's a great Indian success story," Dr. Jacob John, a former virologist of the Christian Medical College (CMC), Vellore had earlier told this Correspondent. A study published in the WHO bulletin showed that using a CTC approach can reduce the cold chain related campaign costs by 50 per cent. ■

Indian Immunologicals plans setting up Rs 300 crore facility in Puducherry

BUSINESS STANDARD
January 9, 2015

Hyderabad-based Indian Immunologicals Limited (IIL), which recently emerged as the world's largest manufacturer of foot-and-mouth disease (FMD) vaccine, has readied plans for setting up a Rs 300-crore facility, which according to the company, will serve as "expansion or for developing a new product".

The proposed "big project" at Puducherry, for which IIL had already "got 30 acres of land", is also part of the government's plan to have enough domestic capacity for meeting an estimated demand of 600 million doses of animal vaccine in the country in the next 3-4 years, an IIL official said.

IIL said sales of FMD vaccine in the country stood at 270 million doses in the last fiscal, while this year it would be 320 million doses. IIL was created by National Dairy Development Board (NDDB) under the Operation Flood programme with the objective of improving livestock health.

On the options being considered for meeting the funding needs, NDDB chairman T Nanda Kumar said, "as of now, we are keen on taking loan. If equity comes, NDDB will invest."

He said IIL first needed to complete the Karakapatla facility near here, where it is developing vaccines for combating chikungunya and Japanese Encephalitis virus (JEV), before taking up the next project.

"It is kept as an insurance for the future. We are readying ourselves for a contingency of either an expansion or developing a new product if in case a new strain appears in the animal gene in the next 2-3 years," said Kumar on the planned new facility.

Speaking to mediapersons on the launch of vaccine for the control of bluetongue disease among sheep, goats and cattle, he said the veterinary care infrastructure in the country was "in poor condition" and the state governments should intervene more to improve services to farmers.

He said IIL would continue to invest in developing new vaccines and presently research was going on in at least dozen

new formulations.

Meanwhile, chief general manager of IIL, GS Reddy, said the bluetongue disease was quite prevalent in south India, covering Andhra Pradesh, Tamil Nadu, Maharashtra, Karnataka and Kerala, affecting over 40 million sheep and 50 million goat population.

He said the company had the necessary infrastructure at its facilities to produce 200 million doses of the bluetongue disease vaccine every year.

The product is intended to serve the government's programme aimed at controlling the spread of the disease by marketing the vaccine at Rs 10 a unit.

The company is also open to marketing it to other South Asian countries and some in Africa. Internationally, the vaccine is available at more than twice the local price. ■

Panacea Biotec gets $13.5 million order from Paho

THE ECONOMIC TIMES
February 4, 2015

Panacea Biotec has received an order worth USD 13.49 million for supplying EasyFive-TT vaccine to global health agency PAHO.

The 5-in-1 vaccine protects infants from 5 potentially deadly diseases: Haemophilus Influenza type B (the bacteria that causes meningitis, pneumonia and otitis), Whooping Cough, Tetanus, Hepatitis B and Diphtheria.

In a BSE filing, Panacea said it has been elected for the supply of pentavalent vaccine DTP-HepB-Hib by the Pan American Health Organisation.

"The company has been awarded for supply of 5.99 million doses of EasyFive-TT (DTP-HepB-Hib) fully liquid Pentavalent Vaccine for calendar year 2015 and 2016 worth USD 13.49 million (equivalent to around Rs. 83.52 crore) to meet the requirements of global immunisation program," it added.

Panacea Biotec Joint MD Rajesh Jain said: "We are pleased with this opportunity of supplying Easyfive-TT vaccines to meet the requirements of PAHO once again after a gap of 3 years."

PAHO is a specialised health agency of the Inter-American System and serves as the Regional Office for the Americas of the World Health Organization. ■

Pfizer, Manipal Hospitals & others join hands to accelerate health tech startups in India

THE ECONOMIC TIMES
February 2, 2015

A group of healthcare entities, including Manipal Hospitals and Narayana Health, have got together with an investor to provide up to Rs 10 crore ($1.6 million) in grants and investments to early-stage startups that seek to enhance access to affordable technology-driven healthcare products and services for low-income masses in India

Apart from the two hospitals, the programme known as Start Health is backed by investor Unitus Seed Fund, PATH, an international non-profit organisation, and pharmaceutical major Pfizer. "Many of the 150 healthcare entrepreneurs we've met over two years weren't ready yet for an investment from us. With StartHealth, we can engage and invest even earlier in their development. There is a massive supply-demand gap for healthcare services in India. If you can create access and affordability, the demand is massive.

Technology can be a game-changer to enable access and affordability," said Dave Richards, managing partner of Unitus Seed Fund.

The partners expect to select up to five startups in 2015. They will get up to Rs 50 lakh ($85,000) of nondilutive capital to fund immediate pre-seed business progress for six to 12 months and hands-on support from PATH, Manipal Hospitals and Narayana Health's staff.

They also get access to expert networks of Pfizer, PATH, Manipal Hospitals, Narayana Health and Unitus in India and globally and facilities of Manipal Hospitals and Narayana Health for pilots and market testing.

"Many of these solutions are developed mostly based on hypothesis and prototype situations without proper and expert clinical evaluation," said Ravichandran Natarajan, senior

vice president and head of corporate relations at Narayana Health. "We believe that our engagement through Start Health initiative will provide right and appropriate platform to healthcare technology entrepreneurs in evaluating the same on an actual scenario of the large low-income population base."

Alongside, seed capital of Rs 1 crore ($165,000) and support from Unitus Seed Fund and its investing partners will be provided to the startups to prepare for growth and then to raise scale-up capital.

"Through our partnership with Unitus...we can improve the efficiency of identifying and pursuing due diligence on such groups, as well as the effectiveness of helping them to develop and scale their businesses," said Dipika Matthias, Director of PATH's Global Health Innovation Hub initiative.

Areas of interest for healthcare innovation for StartHealth partners are low-cost diagnostic and monitoring devices connecting doctors and patients, healthcare cloud IT solutions and innovations for use in labs or clinical settings to improve the quality of care at lower levels of healthcare system, such as primary care clinics. ■

Indian scientists turn coconut oil into biofuel

ZEE NEWS
February 6, 2015

Scientists who have been running the four-stroke diesel engine of a light pick-up truck on coconut oil for the past one year have approached the union government to commercialise the biofuel.

The scientists are attached to the Kochi-based SCMS Institute of Bioscience and Biotechnology Research and Development and the SCMS School of Engineering and Technology.

While the manufacturers of the Tata Ace claim mileage of 16 km to a litre of diesel, the vehicle can run 22.5 km per litre of the biofuel, the scientists say.

"We purchased this brand new vehicle a year back. By now, it has done 20,000 km and has proved beyond doubt that coconut oil can replace diesel. We can provide this product at Rs.40 a litre," C. Mohankumar, who heads the team of six scientists, told IANS.

Mohankumar said they have already applied for a US patent and also approached the union ministry of renewable energy to take this biofuel to its logical conclusion by commercialising it.

"The emission levels are lower than other forms of biodiesel, making it a very eco-friendly product too," said Mohankumar.

Explaining the process, he said 760 litres of biofuel can be produced from the oil of 10,000 coconuts.

"There are also five other by-products. This includes 5,000 kg of husk, 2,500 kg of coconut shells, 1,250 litres of coconut water, around 1,200 kg of cake (that can be used as cattle feed) and 70 litres of glycerol."

"Each of these products has a market value and that's how we are able to commercially supply this biodfuel at Rs.40 a litre," Mohankumar said.

"We have conducted numerous tests on this coconut biofuel that are for anyone to see. It shows that all the parameters are much lower than other biodiesel products," he added.

The study was published in the December 2014 issue of the journal 'Fuel'.

Coconut Development Board (CDB) Chairman T.K. Jose said he had studied the performance of the vehicle that the scientists have been using.

"We (CDB) don't have the funds for taking forward their innovation and hence they have approached the centre. I have gone through all their reports on the biofuel. The emission levels are much less than other similar products," Jose told IANS. ■

Shantha Biotech setting up insulin manufacturing plant in Hyderabad

BUSINESS LINE
January 29, 2015

Shantha Biotechnics, a Sanofi company, is setting up an insulin manufacturing unit at its premises.

The Chief Minister, K Chandrasekhar Rao, formally laid the foundation stone for the plant at Muppireddipalli near here

Speaking on the occasion, Shantha Biotechnics' founder and non-executive chairman K Varaprasad Reddy said the plant would make all varieties of human insulin with technology transfer from Sanofi's facility in Frankfurt. ■

First 3-D culture system for pancreatic cancer developed

BUSINESS STANDARD
January 1, 2015

Scientists have developed a new method to grow human pancreatic tissue in a three-dimensional culture system, paving the way for future personalised treatment approaches for deadly pancreatic cancer.

Pancreatic cancer is one of the most deadly forms of cancer, with only 6 per cent of patients surviving five years after diagnosis, researchers said.

Researchers at the Cold Spring Harbour Laboratory (CSHL) and The Lustgarten Foundation have now developed a new model system to grow both normal and cancerous pancreatic cells in the laboratory.

Their work offers the potential to change the way pancreatic cancer research is done, allowing scientists to interrogate the pathways driving this devastating disease while searching for new drug targets.

Researchers described a three-dimensional "organoid" culture system for pancreatic cancer.

They developed a method to grow pancreatic tissue not only from laboratory mouse models, but also from human patient tissue, offering a path to personalised treatment approaches in the future.

By comparing normal cells to cancer cells, scientists can identify the changes that lead to disease. However, both types of pancreatic cells have been extremely difficult to culture in the laboratory.

The normal ductal cells that are able to develop into pancreatic cancer represent about 10 per cent of the cells in the pancreas, complicating efforts to pinpoint the changes that occur as the tumour develops.

Until now, scientists have been entirely unable to culture human normal ductal pancreatic cells under standard laboratory conditions.

Because of these limitations, most pancreatic cancer research relies on genetically engineered mouse models of the disease, which can take up to one year to generate. "With this development, we are now able to culture both mouse and human organoids, providing a very powerful tool in our fight against pancreatic cancer," said Tuveson. The organoids are entirely made up of ductal cells, eliminating the surrounding cell types that often contaminate samples from the pancreas.

They grow as hollow spheres within a complex gel-like substance filled with growth-inducing factors and connecting fibres. Once they have grown to a sufficient size, the organoids can be transplanted back into mice, where they fully recapitulate pancreatic cancer. ■

Ebola vaccine safe, generates immune response, shows trial

THE HINDU
January 29, 2015

The first trial results of Ebola vaccine at Oxford University suggest the vaccine has an acceptable safety profile and is able to generate an immune response.

"The Ebola vaccine was well tolerated. Its safety profile is pretty much as we had hoped," said professor Adrian Hill of the Jenner Institute at Oxford University who led the trial.

The results suggest that the vaccine is suitable for further testing in West Africa during the current outbreak.

The Ebola vaccine is being co-developed by the US National Institutes of Health (NIH) and pharmaceutical firm GlaxoSmithKline (GSK) against the Zaire strain of Ebola, which is the one circulating in West Africa.

The first doses for use in large scale trials in West Africa have been delivered to Liberia by GSK.

The vaccine uses a single Ebola virus gene in a chimpanzee adenovirus to generate an immune response.

As it does not contain infectious Ebola virus material, it cannot cause a person who is vaccinated to become infected with Ebola.

During the trial, 60 healthy volunteers were vaccinated at the Jenner Institute.

The results showed safety data and immune responses for the volunteers for 28 days after immunisation.

Two people experienced a moderate fever within 24 hours of receiving the vaccine but this passed within a day.

"People typically experienced mild symptoms that lasted for one or maybe two days, such as pain or reddening at the injection site, and occasionally people felt feverish," professor Hill explained.

The primary goal of the trial was to assess safety. However, the scientists also assessed immune responses to Ebola seen in the volunteers before and after vaccination.

Importantly, the vaccine generated immune responses against Ebola in the volunteers.

Levels of antibodies increased over a period of 28 days after vaccination and there was no significant difference in the levels seen at different doses.

Levels of T cells — cellular immunity is the other arm of the body's immune system — peaked at 14 days.

"Larger trials in West Africa are needed to tell whether immune responses are large enough to protect against Ebola infection and disease," the team added.

The Oxford University trial is one of several safety trials of the GSK/NIH vaccine candidate — in the USA, Britain, Mali and Switzerland — that have been fast-tracked in response to the Ebola outbreak in West Africa.

The Oxford University scientists have also begun testing the safety of a candidate booster vaccine against Ebola, to find out whether it could further increase the immune responses.

According to the World Health Organisation (WHO), the Ebola outbreak in West Africa has killed over 8,000 people so far.

The initial findings were published in the New England Journal of Medicine (NEJM).

French scientists develop polymer-based synthetic muscle

POLYMER SOLUTIONS
January 26, 2015

Living organisms are amazing feats of engineering. From complex thought to relatively simple digestion and locomotion, mother nature is truly a masterful designer. For thousands of years, mankind has attempted to emulate nature both in art and science. History is full of talented painters and sculptors who have mimicked natures forms in two and three-dimensional art while ingenious inventors have created things like airplane wings and camera lenses that function with the same principles that give flight and sight to various animals. Recently, French researchers at the Centre National De La Recherche Scientifique have accomplished yet another impressive feat by creating synthetic muscles using a polymer-based contractile gel.

Inspired by nature: In living organisms, nerve signals can be sent from the brain to manifest collective molecular motions that have a macroscopic effect – put simply, animals can contract and relax muscles via the stimulus of protein motors. For just about every living thing, locomotion requires very little thought or consideration, despite the actual complexity of this process. Every time you tense a muscle, tiny protein-based motors engage, each moving mere nanometers at a time. However, when millions of these tiny units work together to pull in the same direction, then the effect is much more powerful.

In order to recreate organic muscles in a synthetic compound, Nicolas Giuseppone, a professor at the University of Strasbourg, and his team at CNRS' Institut Charles Sadron have created a novel polymer gel that can contract and relax with assistance from tiny chains of molecular motors. These nanoscale motors are photosensitive, which means that they are engaged by exposure to light. When activated, the motors twist the polymer chains that are suspended in gel, causing the entire system to contract several centimeters.

Balancing torque and strength: In organic systems, the tension expressed by these complex chains of proteins is kept in check by the sensation of pain. If you've ever lifted weights, you have probably experienced that painful moment when you simply cannot lift anymore, and you have to put down the barbell. CNRS' synthetic muscle gel is not connected to a nervous system, so it obviously cannot experience pain. As a result, there is nothing stopping the tiny motors from continuing to twist. So if the polymer gel is left in direct solar exposure for an extended period of time, the built up energy can be enough for the gel to literally tear itself to pieces.

At this point, the design challenge facing CNRS scientists is figuring out how to deal with the excess energy that is generated when solar power is converted into kinetic energy. Either they have to figure out a way to strengthen the polymer to such a point that its

strength is equal or greater than the maximum torque that the motors could theoretically produce, or they have to develop an energy dump to allow excess kinetic energy to be expelled from the system.

No matter how this challenge is resolved, one thing is certain: this novel, polymer-based gel muscle represents an exciting development that is sure to have broad repercussions on such areas of industry as medical devices and robotics. Imagine a solar-powered robot that can move with the same organic movement as a human being or a medical brace that could improve the users strength with sunlight. Once researchers are able to work the kinks out of this amazing new compound, the engineering applications would be limitless. However, as always, additional testing is required!

Stem cell-grown hair could help those with hair loss

CNET
January 28, 2015

For the first time, researchers have been able to use pluripotent stem cells to generate cells that can grow new hair.

It's been theorised for years, but now human stem cells have resulted in hair growth for the very first time.

"We have developed a method using human pluripotent stem cells to create new cells capable of initiating human hair growth. The method is a marked improvement over current methods that rely on transplanting existing hair follicles from one part of the head to another," said Alexey Terskikh, Ph.D., associate professor in the Development, Aging and Regeneration Program at Sanford-Burnham.

"Our stem cell method provides an unlimited source of cells from the patient for transplantation and isn't limited by the availability of existing hair follicles."

The process started with human pluripotent embryonic stem cells -- that is, stem cells that are capable of developing into any other cell -- which were then developed into neural crest cells. These are cells that can develop into a variety of cells on the head, including brain cells, cartilage, bone and muscle cells.

From the neural crest cell point, the team coaxed the cells to grow into dermal papillae cells, the cells that nourish the skin and regulate follicle growth and formation. When transplanted -- in the case of this study, into hairless mice -- these cells flourish.

Another part of the study examined whether the same result could be achieved using dermal papillae cells taken from the scalps of adult humans. Outside the body, living in culture, these cells are not suitable for hair transplants, since they lost their ability to induce follicle formation. The number of hairs their produced was insignificant.

"In adults, dermal papilla cells cannot be readily amplified outside of the body and they quickly lose their hair-inducing properties," said Terskikh. "We developed a protocol to drive human pluripotent stem cells to differentiate into dermal papilla cells and confirmed their ability to induce hair growth when transplanted into mice."

The researchers say that their research represents the first step towards a cell-based treatment for hair loss, which affects 40 million men and 21 million women in the United States.

"Our next step is to transplant human dermal papilla cells derived from human pluripotent stem cells back into human subjects," said Terskikh. "We are currently seeking partnerships to implement this final step."

Existing drug may treat deadly form of malaria

THE FINANCIAL EXPRESS
February 2, 2015

A drug already approved for treating other diseases in humans may be useful as a treatment for deadly cerebral malaria, according to Harvard researchers.

Researchers discovered a novel link between food intake during the early stages of infection and the outcome of the disease, identifying two molecular pathways that could serve as new targets for the treatment.

"We have known for a long time that nutrition can affect the course of infectious disease, but we were surprised at how rapidly a mild reduction in food intake could improve outcome in a mouse malaria model," said senior author James Mitchell, associate professor of genetics and complex diseases at Harvard T H Chan School of Public Health.

"However, the real importance of this work is the identification of unexpected molecular pathways underlying cerebral

malaria that we can now target with existing drugs," said Mitchell.

Cerebral malaria – a severe form of the disease – is the most serious consequence of infection by the parasite Plasmodium falciparum, resulting in seizures, coma, and death.

Currently there is a lack of safe treatment options for cerebral malaria, particularly for use in children, who represent the majority of cases.

Even patients who receive early treatment with standard antimalarial chemotherapeutic agents run a high risk of dying, despite clearance of the parasite, researchers said.

Moreover, around 25 per cent of survivors develop neurological complications and cognitive impairment.

Lead authors Pedro Mejia and J Humberto Trevino-Villarreal found that leptin – a hormone secreted from fat tissue with roles in suppressing appetite, but also in activating adaptive immune and inflammatory responses – is increased upon infection in a mouse model of cerebral malaria, and turns out to be a major bad actor in promoting neurological symptoms and death.

Mejia, Trevino-Villarreal and colleagues showed that reducing leptin using a variety of means, either genetically, pharmacologically, or nutritionally by reducing food intake during the first two days of infection, protected against cerebral malaria.

The researchers also found that leptin acted primarily on cytotoxic T cells by turning on the well-studied mTOR protein, for which pharmacologic inhibitors are readily available.

In their animal model, treating mice with the mTOR inhibitor rapamycin protected them against the neurological complications of cerebral malaria.

Protection was due in part to a preservation of the blood brain barrier, which prevented the entry of blood cells carrying the parasites into the brain.

As rapamycin is already FDA-approved for use in humans, trials in humans for cerebral malaria treatment with this drug may be possible, according to the researchers.

Machines enhanced with human ability to smell

BIOTECNIKA

In a first, an Indian-origin researcher from the University of Manchester has created a biosensor that can help machines smell the way humans do. The new generation of biosensors with an acute ability to sniff out problems can help machines smell when food has gone bad or how much pollution is in the atmosphere.

"It has been challenging to get machines to be able to differentiate between smells that are mirror images of each other, which was a real barrier to creating machines which are able to smell as well or better than humans," explained professor Krishna Persaud, lead author of the paper.

To develop the biosensor, Persaud along with colleagues from University of Bari in Italy utilised an odourant-binding Protein. Such proteins are found in the mucus of the nose which work olfactory receptors helping us to create our perception of smell.

The team has found a method of manufacturing these proteins in quantities that would allow them to be used in biosensors. Using a type of transistor incorporating these proteins, the scientists were able to measure the unique changes in current as the proteins reacted to odours and record them.

This is, in effect, the machine smelling the odour and then sending the message which can then be decoded. The system is incredibly sensitive with a detection limit that approaches that of the human nose. "We have produced a new chemical sensor platform. It will allow much better sensors to be developed and these could have many uses in industry," Persaud added.

Spain uses stem cell therapy to treat damaged hearts

USA NEWS.COM
January 30, 2015

A Spanish hospital has successfully used stem cells culled from healthy donors to treat seven heart attack victims, in what officials said was a world first.

Madrid's Gregorio Maranon hospital plans to treat 55 patients in all with the technique in a clinical trial, the regional Madrid government which runs the hospital said in a statement.

"Seven patients have already been operated on and they have progressed very well despite having suffered serious damage to their heart tissue," it added.

It is the first time that allogeneic cells -- stem cells that come from another person -- have been used to repair damage to a heart caused by a heart attack, the statement added.

A heart attack happens when the organ is starved of oxygen, such as when a clot blocks the flow of blood to the heart.

As the heart heals, the dead muscle is replaced with scar tissue, but because this does not beat like healthy heart muscle the ability to pump blood around the body is reduced.

While patients with mild heart failure can live a relatively normal life with the help of drugs, those with severe heart failure can suffer prolonged pain and distress because everyday tasks such as doing the shopping or taking a shower leave them exhausted.

Doctors around the world are looking at ways of "regenerating" the heart to replace the scar tissue with beating muscle.

Stem cells figure prominently in their plans although they have up until now involved the patient's own stem cells.

While it takes 4-8 weeks to process a patients' own stem cells to be used in therapy, donor cells can be processed and stored and are available for immediate use, the hospital's head of cardiology, Francisco Ferandez-Avila said in the statement.

"Besides this very important advantage, this technique allows for the selection of donors whose cells show the greatest potential to repair" heart tissue, he added.

"Before being processed, the allogeneic cells are exhaustively studied and only those that functioned best are selected," he added.

The cells are injected into the heart through a coronary artery.

The clinical trial is partially financed by the European Union. The hospital is coordinating the study which has involved the cooperation of about 20 European bodies. ■

Now, a smartphone device that can diagnose HIV in 15 minutes

F INDIA
February 6, 2015

A team of researchers from Columbia University has developed a low-cost smartphone accessory or dongle that can perform a test that simultaneously detects three infectious disease markers from a finger prick of blood in just 15 minutes.

Led by Samuel K Sia, associate professor of biomedical engineering at Columbia's School of Engineering and Applied Science, the device replicates for the first time all mechanical, optical, and electronic functions of a lab-based blood test.

Specifically, it performs an enzyme-linked immunosorbent assay (ELISA) without requiring any stored energy as all necessary power is drawn from the smartphone.

"It performs a triplexed immunoassay not currently available in a single test format, HIV antibody, treponemal-specific antibody for syphilis, and non-treponemal antibody for active syphilis infection," Sia explained.

The small device that easily connects to a smartphone or computer was recently piloted by health care workers in Rwanda who tested whole blood obtained via a finger prick from 96 patients.

"A full laboratory-quality immunoassay can be run on a smartphone accessory," Sia noted. This kind of capability can transform how health care services are delivered around the world.

Early diagnosis and treatment in pregnant mothers can greatly reduce adverse consequences to both mothers and their babies.

The team developed the dongle to be small and light enough to fit into one hand and to run assays on disposable plastic cassettes with pre-loaded reagents, where disease-specific zones provided an objective read-out, much like an ELISA assay.

Sia estimates the dongle will have a manufacturing cost of $34, much lower than $18,450 that typical ELISA equipment runs.

During the field testing in Rwanda, the vast majority of patients (97 percent) said they would recommend the dongle because of its fast turn-around time, ability to offer results for multiple diseases and simplicity of procedure.

"By increasing detection of syphilis infections, we might be able to reduce deaths by 10-fold. We might be able to scale up HIV testing at the community level with immediate antiretroviral therapy that could nearly stop HIV transmissions and approach elimination of this devastating disease," the authors concluded. ■

Cereal crops that survive flooding created

THE TIME OF INDIA
February 8, 2015

Researchers have bred a barley variety which is better able to tolerate waterlogging and flooding.

Researchers at The University of Nottingham, UK, and colleagues had previously identified the mechanism used by plants in stress conditions to sense low oxygen levels.

They have now used advanced breeding techniques to reduce yield loss in barley in water-logged conditions.

"We now know how to breed barley cultivars more tolerant to waterlogging and flooding," said Michael Holdsworth, professor of Crop Science in the School of Biosciences.

"Barley cultivars with the capability to withstand waterlogging have excellent growth, superior yields, retain their green appearance due to chlorophyll retention and have a more efficient metabolism even in low oxygen conditions," said Holdsworth.

Plants starved of oxygen cannot survive flooding for long periods of time. Persistent flooding and saturated arable land can wipe out crops and reduce harvests so the search for flood tolerant crops is a key target for global food security, researchers said.

Barley is comparatively more susceptible to waterlogging than other cereals. Average yields can be reduced by up to 50 per cent as a result of waterlogging.

Resistance to this stress is an important objective of breeding efforts in high-rainfall areas of the world.

"We now have the strategy developed for plant breeding to select for enhanced tolerance to waterlogging in barley and other crops," Holdsworth said. ■

New Bt cotton hybrid to boost yield

DECCANHERALD
February 1, 2015

The next growth area in Indian cotton farming may come from newer hybrids of Bt cotton, which allow farmers to plant more cotton in the same area.

Almost 95 per cent Indian cotton farmers already use the genetically modified Bt cotton.

When tested in the cotton belts of the Vidarbha and Marathwada regions, several next-generation Bt cotton hybrids, planted in high density in the fields, gave farmers 20 per cent hike in their income.

At least two private companies—Mahyco and Ankur Seeds—were involved in developing these hybrids, tested successfully on an experimental basis in Aurangabad, Jalna, Beed, Jalgaon, Dhule, Yavatmal and Wardha.

"Development and deployment of high-density planting to maximise yield potential, popularising the system, and mechanisation of cotton picking and harvesting is the way forward for Bt cotton in India," said Bhagirath Choudhary, Director (India) of the International Service for the Acquisition of Agro-biotech Applications (ISAAA), a global lobby group that promotes genetically modified (GM) crops.

The maximum number of regular bushy cotton plants that can be planted in a hectare of land currently is 55,000. In the high-density planting system (HDPS), scientists intend to plant 1-2 lakh cotton plants in the same hectare of land. The spacing between two plants could be as low as 20 cm, instead of 90 cm-1 m for conventional cotton.

These high-density plants are straighter and the bolls are closer to the main stem, allowing mechanical harvesting.

"The HDPS is now being conceived as an alternate production system having a potential for improving productivity and profitability,

increasing efficiency, reducing input costs and minimising risks associated with India's cotton production system," said K R Kranthi, director of the Central Institute of Cotton Research, Nagpur.

In 2014, India cultivated 11.6 million hectares of Bt cotton, planted in almost 95 per cent of that area. More than 77 lakh farmers cultivate the GM crop, said the ISAAA in a report released last week.

While regulatory authorities approved three hybrids in 2001, more than 700 types of Bt cotton seeds are now available in the Indian market.

India has tripled its cotton production from 13 million bales to 40 million bales in the last 13 years, and is projected to overtake China to become to world's biggest cotton-producer in the near future. Currently, both produce 25 per cent of the global market share. ■

GMOs with health benefits have a large market potential

SCIENCE DAILY
January 13, 2015

Genetically modified crops with an increased vitamin and/or mineral content have large potential to improve public health, but their availability for consumers is still hampered, as a result of the negative public opinion. Research from Ghent University, recently published in Nature Biotechnology, has demonstrated that these crops have a promising market potential.

Over the last years, various GM crops with health benefits have been developed in which genes, mostly originating from other organisms, have been added. Notable examples include rice enriched with pro-vitamin A (also known as 'Golden Rice') and folate-enriched rice, developed at Ghent University.

Fifteen years after the development of 'Golden Rice', which was the first GMO with health benefits, the developers of such transgenic biofortified crops have little reason to celebrate. To date, none of these GMOs are approved for cultivation, unlike GMOs with agronomic traits. Despite this, six major staple crops have been successfully biofortified with one or more vitamins or minerals. Clearly, these GMOs with health benefits have great potential. In a recent study, from Ghent University, not only the impact of GM crops on human health, but also their market potential was convincingly demonstrated.

MARKET POTENTIAL

Research at UGent reveals that consumers are willing to pay more for GMOs with health benefits, with premiums ranging from 20% to 70%. This differs from GMOs with farmer benefits, which are only accepted by consumers when they are offered at a discount.

Especially in regions, such as China and Brazil -- which are considered as key target markets for these nutritionally improved crops -- , where a large part of the population suffers from nutrient deficiencies, the potential market share of these GMOs is high.

IMPROVING PUBLIC HEALTH

Several studies show that these GMOs have positive impacts on human health. As expected, the enhancement of multiple micronutrients in the same crop by genetic modification, yields the best results. This method generates aggregated health benefits at a relatively low cost.

VALUABLE ALTERNATIVE TO TACKLE MALNUTRITION

Although GMOs with health benefits are not a panacea for eliminating malnutrition, they offer a complementary and cost-effective alternative when other strategies are less successful or feasible. ■

Plant extract can help smokers quit

ZEE NEWS
December 25, 2014

A plant extract commonly used in eastern Europe to help smokers kick the habit, appears to work much better than nicotine replacement patches and gums, scientists say.

Cytisine is an alkaloid extract from the laburnum or golden rain tree (Laburnum anagyroides), which grows all over Europe. It works by blocking nicotine's access to the brain's pleasure receptors.

Like nicotine, cytisine is toxic when ingested in large amounts but is safe at low doses. It is produced commercially mainly in Bulgaria and Poland, and has been used as a quitting aid in eastern European countries since the 1960s.

Researchers in New Zealand have conducted a fresh trial of cytisine. They recruited 1,310 smokers who intended to quit and gave exactly half of them cytisine as a course of tablets, taken daily

in diminishing doses for 25 days.

The other half received standard nicotine replacement therapy (NRT) - either as patches, gums or lozenges - for two months, 'New Scientist' reported.

The researchers noted the number of people who managed to abstain from smoking at one week, one month, two months and six months into the trial.

Throughout, they found that people taking cytisine were less likely to have smoked than those using NRT. After six months, 143 of the 655 cytisine recipients were still not smoking compared with 100 in the NRT group.

People who received cytisine were slightly more likely to experience side effects, including nausea, vomiting and sleep disturbance, but these were never serious, according to study leader Natalie Walker of the University of Auckland's National Institute for Health Innovation.

Walker said cytisine is more affordable than other quitting aids.

For example, it costs just USD 20 to USD 30 for a 25-day course of treatment, versus USD 100 to USD 700 for a two-month course of NRT depending on the product and who supplies it, or around USD 500 for a three-month course of varenicline (Champix), a drug that works in a similar way to cytisine.

Cytisine is sold as Tabex by Sopharma, a company based in Bulgaria, and as Desmoxan by Aflofarm Pharma of Poland. ■

Kenyan top doctors support agri-biotech, calls for lifting of GM ban

ISAAA
December 17, 2014

Kenyan medical practitioners under the umbrella body - Kenya Medical Association (KMA), have voiced their views in support of agricultural biotechnology. During a recent stakeholders meeting in Nairobi, organized by the Kenya University Biotech Consortium (KUBICO), the KMA chairman Dr. Elly Nyaim supported KUBICO's call on the government to lift the 2012 ban on importation of GM food products. This would allow scientists to deliver current GM crops under research to farmers, who have been waiting in earnest for the products.

The doctors expressed willingness to work with the academia and other stakeholders in educating the public about the safety of GM foods, acknowledging the prevailing gross misinformation about GMOs. According to Dr. Simon Mwangi, a general physician, medics and biotechnologists should work together to improve the living standards of the people. He called on a more collaborative working relationship between biotechnologists and medics adding that doctors need inputs from biotechnologists to solve current health problems brought about by nutritional gap in foods consumed by patients. "From a medical perspective, GM foods have been ascertained as safe for human consumption," said Dr. Mwangi.

KUBICO chairman, Dr. Richard Odour informed the forum that foods such as sweet potato and sorghum are essential part of preventive programs aimed at strengthening the immune system in the human body. He added that biotechnology can make them even more nutritious and Kenyan scientists have what it takes to transform these crops, he said.

Synthetic amino acid enables safe, new biotechnology solutions to global problems

YALE NEWS
January 21, 2015

Scientists from Yale have devised a way to ensure genetically modified organisms (GMOs) can be safely confined in the environment, overcoming a major obstacle to widespread use of GMOs in agriculture, energy production, waste management, and medicine.

The Yale researchers rewrote the DNA of a strain of bacteria so that it requires the presence of a special synthetic amino acid that does not exist in nature to activate genes essential for growth. Amino acids are the building blocks of proteins, which carry out life's functions. This new method of biocontainment, reported online on Jan. 21 in the journal Nature, solves a longstanding problem in biotechnology.

"This is a significant improvement over existing biocontainment approaches for genetically modified organisms," said Farren Isaacs, assistant professor in the

Department of Molecular, Cellular, and Developmental Biology and the Systems Biology Institute at West Campus, and senior author of the paper. "This work establishes important safeguards for organisms in agricultural settings, and more broadly, for their use in environmental bioremediation and even in medical therapies."

Isaacs, Jesse Rinehart, Alexis Rovner, and fellow synthetic biologists at Yale call these new bacteria genomically recoded organisms (GROs) because they have a new genetic code devised by the team of researchers. The new code allowed the team to link growth of the bacteria to synthetic amino acids not found in nature, establishing an important safeguard that limits the spread and survival of organisms in natural environments.

In a second study, Isaacs, Ryan Gallagher, and Jaymin Patel at Yale devised a strategy to layer multiple safeguards that also limit growth of GMOs to environments that contain a different set of synthetic molecules. Published Jan. 21 in the journal Nucleic Acids Research, this study describes a complementary set of distinct and portable safeguards capable of securing a wide range of organisms.

These safe GMOs will improve efficiency of such engineered organisms, which are now being used in closed systems, such as the production of pharmaceuticals, fuels, and new chemicals. Concerns about use of GMOs in open environments, however, has limited their adoption in other areas.

The authors also say that the new code paired with artificial amino acids will allow scientists to create safer GMOs for use in open systems, which include improved food production, designer probiotics to combat a host of diseases, and specialized microorganisms that clean up oil spills and landfills.

"As synthetic biology leads to the emergence of more sophisticated GMOs to address these grand challenges, we must assume a proactive role in establishing safe and efficacious solutions for biotechnology, similar to those who worked to secure the Internet in the 1990s." Isaacs said.

China underlines cautious approach to biotech crops

REUTERS
February 3, 2015

China will continue to promote research into genetically modified crops while maintaining strict controls on safety of the technology, a top agriculture official said on Tuesday, underscoring Beijing's cautious approach towards biotechnology.

The comments came after a major policy document, known as the "number one document", called for strengthening of GMO research and safe management of the technology, as well as educating the public on the issue.

It was the first time that the document, released early each year and focusing on agriculture, had explicitly addressed the increasingly fervent debate among the Chinese public around safety of GMO foods. That prompted speculation in local media about a possible shift in the government's position.

But Han Jun, deputy head of the Communist Party's office on rural affairs, said the new document was "consistent" with current policy on biotech.

The GMO debate had become a "social problem" and people needed a more objective understanding of the technology, he said.

China has poured billions of yuan into developing GMO seeds but has not dared to permit cultivation of biotech varieties of feed and food crops, citing consumer concerns over safety.

Its position is also thought to be impacting the approval for import of genetically modified crops, which faces long delays.

The government has already made some attempts to clear up worries about GMOs, launching a national media campaign last year.

But Han said that it remained an "extremely sensitive" issue for all of Chinese society. "It's a hot topic for everyone in their daily life."

While recognizing the problem of public perception, Chinese scientists are increasingly impatient with the government's approach.

"Scientists are in a hurry, companies are in a hurry, farmers are also in a hurry. But our government departments need to speed up," Huang Dafang, research fellow and former director of the Biotechnology Research Institute at China's Academy of Agricultural Sciences told reporters last week.

He also questioned why the government had stalled commercialization of GMO crops.

"New strains are still not being approved. Is it because of safety? No, it's because of government process."

Han added that China follows international standards on safety and management of its biotech research in areas such as genetically modified rice and corn, and said that Beijing had no choice but to continue supporting the technology.

"China, a big country with 1.3 billion people and its agricultural development facing increasingly serious environmental constraints, cannot afford to fall behind in research of GMOs.

Novel mechanism may lead to better TB control

THE HINDU
January 8, 2015

A recent finding by scientists of a novel mechanism in which one of the proteins of Mycobacterium tuberculosis suppresses the adaptive immune response in the host could lead to development of new drugs to control the disease.

The team of scientists led by Dr. Sangita Mukhopadhyay, Group Leader, Laboratory of Molecular Cell Biology at the Centre for DNA Fingerprinting and Diagnostics (CDFD) has found that Mycobacterium tuberculosis protein ESAT-6 suppresses host's protective functions. They identified that ESAT-6 directly binds with host molecule beta-2 microglobulin and inhibits antigen presentation to CD8 T-cells which play a key role in protective immune response mechanism of the host.

Dr. Sangita said the CD8 T-cells recognise the infected immune cells and directly kill them.

The ESAT-6 protein through its interaction with the host molecule would delay or inhibit the CD8 T-cells immune response, which was important to control the disease.

The novel mechanism involving the interaction between ESAT-6 and beta-2 microglobulin not only shed new light on host-pathogen relationship, but could open up new avenues for development of novel drugs or vaccine for TB therapy, she added.

Dr. Sangita said beta-2 micro globulin would be free to do its protective role once the interacting domain gets neutralised and the process would help in antigen presentation and activation of CD8 T-cells.

The work of the CDFD team was published in October 2014 issue of PLoS Pathogens.

The scientists are now planning to develop an ESAT-6-beta-2m crystal structure for designing of small molecule inhibitor. "Once that is done, we can go for in-vitro experiments initially and animal studies subsequently", she added.

She said there was a need to develop newer drugs for TB in view of the growing incidence of multi-drug resistance to the disease.

Quoting WHO statistics, she said about 2.3 million cases occur annually in India, one-fifth of global incidence, with one death occurring every 23 seconds. It has also has one of the highest number of multi-drug-resistant patients.

As estimated by WHO, 300,000 people die from TB each year in India. There were about 1.5 million deaths in the world in 2013 — about one death every 21 seconds. It is estimated that about 40 per cent of Indians are infected with TB bacteria, the vast majority of whom have latent rather than active TB disease.

Scientists find drug candidate for TB, malaria

DECCAN HERALD
January 15, 2015

A common drug against the two big killer diseases was a dream for scientists for years. But biologists in Delhi have successfully tested the candidate–a peptide (type of protein) molecule called M5–in the laboratory and found that it reduces the diseases load by 80 per cent in TB and malaria.

"It is promising, but several years of research is required before we come anywhere close to trying this molecule as a drug. In the next step, we will test this protein in malaria infected mice to see the response," Anand Ranganathan, one of the principal investigators at International

Centre for Genetic Engineering and Biotechnology (ICGEB), Delhi, told Deccan Herald.

When studied in the laboratory, M5 not only inhibits pathogen's entry to human cells by 80 per cent in case of TB and malaria, but it was also effective against drug resistant-strains of malaria causing Plasmodium Falciparum parasite that has emerged as a public health concern.

Drugs available at present for treatment of both these infections have been failing in cases with resistant strains of pathogens, causing wide-spread alarm.

While globally there was 8.6 million new cases of TB with 1.3 million deaths in 2012, the incidence of malaria, too, is equally staggering at 207 million cases with 6, 27,000 deaths.

"We were looking at an universal target and found M5 is promising. We will keep on modifying the molecule," said Gobardhan Das, one of the team members from Jawaharlal Nehru University (JNU).

Besides Ranganathan and Das, the team includes Pawan Malhotra of ICGEB and several young researchers from ICGEB, JNU and All India Institute of Medical Sciences. The research findings have been published in the January 14 issue of "Nature Communications".

"It is a fantastic paper, though drug development is a log way off. Four young groups have come together for this important discovery, breaking the boundary of academic institutions," said Samir K Brahmachari, former director-general of Council of Scientific and Industrial Research.

The Delhi team pursued an innovative approach as the target was a host (human) protein, rather than one in the pathogen. "Most drugs target pathogenic proteins. As a result, after few years the pathogen becomes resistant to the drugs. This will not happen with M5," said Ranganathan.

M5, on the other hand, targets two human proteins ICAM-1 (TB) and its cousin ICAM-4 (malaria) and inhibits the invasion of human cells of two very different pathogens significantly. ■

Cooling brain protein could aid search for Alzheimer's treatment

REUTERS
January 14, 2015

Scientists have found a mechanism that kicks in when the body is cooled and prevents the loss of brain cells, and say their find could one day lead to treatments for brain-wasting diseases such as Alzheimer's.

Studying mice, the researchers were able to simulate the effects of body cooling and pick apart the workings of a so-called "cold-shock" protein in the brain, RBM3, which has previously been linked with preventing brain cell death.

"We've known for some time that cooling can slow down or even prevent damage to brain cells, but reducing body temperature is rarely feasible in practice (because) it's unpleasant and involves risks such as pneumonia and blood clots," said Giovanna Mallucci who led the research.

"By identifying how cooling activates a process that prevents the loss of brain cells, we can now work toward finding a means to develop drugs that might mimic the protective effects of cold on the brain."

Scientists already know that lowering body temperature can protect the brain. People can survive hours after a cardiac arrest with no brain damage after falling into icy water, for example, and artificially cooling brains of babies with oxygen deprivation at birth can also protect against brain damage.

Cooling -- and hibernation in animals -- prompts production of certain brain proteins known as "cold-shock" proteins. One of these, RBM3, has been linked with preventing the death of brain cells and synapses, but scientists are not sure how it works.

Knowing how these proteins affect synapse regeneration might help researchers find a way of mimicking them without the needing to cool the body down.

Mallucci's team reduced healthy mice's body temperatures to 16-18 degrees Celsius -- similar to that of a hibernating small mammal -- for 45 minutes and found that the mice's synapses dismantled on cooling and regenerated when re-warmed.

The team then repeated the cooling in mice that had been specially bred with features of neurodegenerative diseases like Alzheimer's and found the capacity for synapse regeneration fell as the disease progressed, and that RMB3 levels also dropped.

When the scientists artificially boosted levels of RBM3 they found it protected the Alzheimer's mice, preventing synapse and brain cell depletion.

Hugh Perry, chairman of Britain's Medical Research Council's neurosciences and mental health board, which funded the research, said the finding may be important step forward.

"We now need to find something to reproduce the effect of brain cooling. We need to find drugs which can induce the effects of hibernation and hypothermia ■

Soon, cancer cells detecting 'Endoscope' to destroy tumors too

DNA
January 4, 2015

Scientists are working to upgrade the tool used to examine and detect cancer and other illnesses, called Endoscope, so that it can zap tumors as well. The biomedical advancement, which is under development at the University at Buffalo, could make chemotherapy more efficient, reduce its side effects and improve how doctors treat some of the most deadly forms of cancer.

Ulas Sunar, PhD, a research assistant professor in UB's Department of Biomedical Engineering sad that they were developing a novel endoscopic device that would improve the ability to detect and destroy cancer cells. The new endoscope utilizes spatial frequency domain imaging. This new technique corrects the image contrast problem by projecting patterns of light at different frequencies on the cancer cells. This results in a high-contrast map of the tumor environment.

Chemotherapy drugs will be delivered intravenously. But unlike conventional treatment, the drugs will be encapsulated in tiny liposomes called nanoballoons. This technology - under development by Jonathan Lovell, PhD, UB assistant professor of biomedical engineering - carries the drugs to the tumor while shielding them from healthy cells, thus reducing side effects. Upon reaching the cancer cells, doctors strike the nanoballons with the endoscopic light beam, causing them to pop open and release the drug directly at the tumor.

To effectively target the nanoballoons, doctors need to control the light beam. Sunar is developing a "digital mask" that adjusts the beam's intensity as well as manipulates its shape down to micron (one millionth of a meter) precision using a computer. The system could be especially useful for treating ovarian cancer that has spread to the abdomen, as well as cancer in the lungs, gastrointestinal tract, mouth and other internal organs, he said.

Sunar will spend much of 2015 developing the system, after which it would be tested on animal models. Upon completion of the grant in 2016, he expects to begin a pilot study with Shashikant Lele, MD, clinical chief of gynecologic oncology at Roswell Park Cancer Institute, and professor of gynecology and obstetrics at the UB School of Medicine and Biomedical Sciences.

Using stem cells to learn how to help treat dementia

TECH TIMES
January 3, 2015

Stem cells taken from people with an inherited type of dementia have been cultured in a lab with a hope of identifying possible new treatments, researchers in Belguim say.

Studying the stem cells with a mutation that predisposes people to development of frontotemporal dementia -- a form of the condition found in about half the dementia cases that develop before age 60 -- the researchers report identifying a defect that interferes with normal neurological development.

When the defect was targeted and corrected, the stem cells partially returned to normal, they said in the journal Stem Cell Reports.

Frontotemporal dementia, which can bring on behavioral symptoms or emotional and language disorders, is caused by damage to neurons in regions of the brain known as the frontal and temporal lobes.

Mutations in one gene known as progranulin (GRN) are often linked with frontotemporal dementia, but such GRN mutations have been difficult to study in usual animal lab experiments, since they do not display all the symptoms of the human version of the disorder, researchers say.

"Use of induced pluripotent stem cell (iPSC) technology makes it possible to model dementias that affect people later in life," says senior study author Catherine Verfaillie of KU Leuven.

The technology takes skin cells from patients and reprograms them into embryonic-like stem cells, which in turn can become specific cell types relevant to the study of a particular disease, she explains.

The researchers created iPSCs from skin cells taken from three patients who carry the GRN mutation, then turned those immature cells into specific mature

cells called cortical neurons, which are the most affected type of cell seen in frontotemporal dementia.

A defect in the GRN-mutated stem cells affected a particular signaling pathway, known as the Wnt pathway, which is vital to neuronal development, but genetic correction restored the iPSCs cell's ability to mature into cortical neurons, the researcher found.

"Our findings suggest that signaling events required for neurodevelopment may also play major roles in neurodegeneration," says study co-author Philip Van Damme of the Leuven Research Institute for Neuroscience and Disease.

"Targeting such pathways, as for instance the Wnt pathway presented in this study, may result in the creation of novel therapeutic approaches for frontotemporal dementia."

Further study of what goes on in GRN-mutated cells could help identify some precise molecular targets for possible drug treatments for dementia, the researchers note. ■

Study claims viruses might have made humans smarter

PUNE MIRROR
January 14, 2015

A new study from Lund University in Sweden indicates that inherited viruses that are millions of years old play an important role in building up the complex networks that characterise the human brain.

Researchers have long been aware that endogenous retroviruses constitute around five per cent of our DNA. For many years, they were considered junk DNA of no real use, a side-effect of our evolutionary journey.

In the current study, Johan Jakobsson and his colleagues show that retroviruses seem to play a central role in the basic functions of the brain, more specifically in the regulation of which genes are to be expressed, and when. The findings indicate that, over the course of evolution, the viruses took an increasingly firm hold on the steering wheel in our cellular machinery. The reason the viruses are activated specifically in the brain is probably due to the fact that tumours cannot form in nerve cells, unlike in other tissues.

"We have been able to observe that these viruses are activated specifically in the brain cells and have an important regulatory role. We believe that the role of retroviruses can contribute to explaining why brain cells in particular are so dynamic and multifaceted in their function. It may also be the case that the viruses' more or less complex functions in various species can help us to understand why we are so different", says Johan Jakobsson, head of the research team for molecular neurogenetics at Lund University.

The article, based on studies of neural stem cells, shows that these cells use a particular molecular mechanism to control the activation processes of the retroviruses. The findings provide us with a complex insight into the innermost workings of the most basal functions of the nerve cells. At the same time, the results open up potential for new research paths concerning brain diseases linked to genetic factors.

"I believe that this can lead to new, exciting studies on the diseases of the brain. Currently, when we look for genetic factors linked to various diseases, we usually look for the genes we are familiar with, which make up a mere two per cent of the genome. Now we are opening up the possibility of looking at a much larger part of the genetic material which was previously considered unimportant. The image of the brain becomes more complex, but the area in which to search for errors linked to diseases with a genetic component, such as neurodegenerative diseases, psychiatric illness and brain tumours, also increases". ■